

John J. Duffy (SB No. 6224834)  
Kevin M. Ringel (SB No. 6308106)  
Margaret C. Redshaw (SB No. 6327480)  
**SWANSON, MARTIN & BELL, LLP**  
330 N Wabash, Suite 3300  
Chicago, Illinois 60611  
Tel: (312) 321-9100; Fax: (312) 321-0990  
jduffy@smbtrials.com  
kringel@smbtrials.com  
mredshaw@smbtrials.com

Marc G. Cowden (SB No. 169391)  
Adam Stoddard (SB No. 272691)  
**SHEUERMAN, MARTINI, TABARI,  
ZENERE & GARVIN**  
1033 Willow Street  
San Jose, California 95125  
Tel: (408) 288-9700; Fax: (408) 295-9900  
mcowden@smtlaw.com  
astoddard@smtlaw.com

*Counsel for Defendant Chart Inc.*

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION**

IN RE PACIFIC FERTILITY CENTER  
LITIGATION

Case No. 3:18-cv-01586-JSC

**DEFENDANT CHART INC.'S NOTICE OF  
MOTION AND MOTION TO EXCLUDE  
THE EXPERT REPORT AND OPINION  
OF DR. ANAND DAVID KASBEKAR AND  
DR. DAVID WININGER**

Date: March 4, 2021  
Time: 9:00 a.m.  
Judge: Hon. Jacqueline Scott Corley  
Place: Zoom

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DEFENDANT'S MOTION TO EXCLUDE KASBEKAR AND WININGER  
CASE NO. 3:18-CV-01586-JSC

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**NOTICE OF MOTION AND MOTION**

TO ALL ATTORNEYS AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on March 4, 2021, at 9 a.m., before the Honorable Jacqueline Scott Corley, Defendant Chart Inc. will and does hereby move the Court for an Order excluding opinions of Dr. Anand David Kasbekar and Dr. David Wininger, which are unsupported and unreliable under Federal Rules of Evidence 702, as well as *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) and its progeny.

This motion is based on this Notice of Motion, the following Memorandum of Points and Authorities, the Declaration of Kevin M. Ringel, pleadings and other documents on file in this action, any oral or documentary evidence or argument as may be requested by the Court, and any other information the Court deems proper and necessary.

Dated: December 22, 2020

Respectfully submitted,

By: /s/ Kevin Ringel

John J. Duffy (SB No. 6224834)  
Kevin M. Ringel (SB No. 6308106)  
**SWANSON, MARTIN & BELL, LLP**  
330 N Wabash, Suite 3300  
Chicago, Illinois 60611  
Tel: (312) 321-9100; Fax: (312) 321-0990  
jduffy@smbtrials.com  
kringel@smbtrials.com

Marc G. Cowden (SB No. 169391)  
Adam Stoddard (SB No. 272691)  
**SHEUERMAN, MARTINI, TABARI, ZENERE  
& GARVIN**  
1033 Willow Street  
San Jose, California 95125  
Tel: (408) 288-9700; Fax: (408) 295-9900  
mcowden@smtlaw.com  
astoddard@smtlaw.com

*Counsel for Defendant Chart, Inc.*

**MEMORANDUM OF POINTS AND AUTHORITIES**

Defendant Chart Inc. (“Chart”) respectfully submits this memorandum of points and authorities in support of its motion to exclude the opinion testimony of Plaintiffs’ liability experts, Dr. Anand David Kasbekar and Dr. David Wininger.

**I. INTRODUCTION**

The gravamen of Plaintiffs’ product liability case is their allegation that a Chart MVE 808 cryopreservation freezer (“Tank 4”) contained a design and/or manufacturing defect that caused the loss of Plaintiffs’ cryogenically stored tissue at Pacific Fertility Center’s (“PFC”) facility on March 4, 2018. Plaintiffs’ two liability experts, Kasbekar and Wininger, have issued Rule 26(a)(2)(B) reports and have been deposed.<sup>12</sup> Expert discovery is now closed and neither expert has offered an admissible opinion to support the causation element of Plaintiffs’ product liability case against Chart.

Plaintiffs stumbled badly in their expert work in this case. First, they never disclosed a cryogenic engineer to opine on the design and manufacture of the cryogenic freezer and, specifically, the cryogenic aspect of the causation element of their case. Cryogenic engineering is a highly specialized field that requires unique education and training in select PhD. programs such as M.I.T., the University of Wisconsin, or Georgia Tech. Graduates of these programs go to NASA<sup>3</sup>, Los Alamos National Laboratory or FermiLab<sup>4</sup>.

<sup>1</sup> Kasbekar’s November 6, 2020 report, December 4, 2020 rebuttal report, transcripts of his depositions on April 13, 2019, November 25, 2020, and December 15, 2020 are attached to the supporting declaration of K. Ringel as exhibits A, B, C, D and E, respectively.

<sup>2</sup> Wininger’s November 6, 2020 report and November 30, 2020 deposition are attached to the supporting declaration of K. Ringel as exhibits F and G, respectively.

<sup>3</sup> See <https://cryo.gsfc.nasa.gov/> (last visited Dec. 21, 2020).

<sup>4</sup> See <https://td.fnal.gov/cryogenics/> (last visited Dec. 21, 2020).

1 Chart disclosed Dr. Franklin Miller, who obtained his PhD. in cryogenic engineering from  
2 M.I.T., worked at NASA, and now teaches and researches in cryogenic engineering at the  
3 University of Wisconsin. Plaintiffs disclosed Kasbekar, a well-travelled, jack-of-all trades  
4 engineer with essentially no experience in the cryogenic issues at the heart of the case against  
5 Chart.

6  
7 To the extent Kasbekar tried to teach himself cryogenic engineering for this case, he came  
8 up well short. His methodology is flawed and his analysis is riddled with errors and omissions.  
9 Kasbekar's primary conclusion is that a crack in a weld of a fill tube resulted in the complete loss  
10 of vacuum seal which then prompted 14 inches of liquid nitrogen (LN2) to rapidly evaporate from  
11 Tank 4 in only 22 hours, undetected by lab personnel. Even though he had ready access to an  
12 exemplar MVE 808 purchased by Plaintiffs, Kasbekar did not bother to test his hypothesis that  
13 that much LN2 could actually evaporate in that short time-period if the tank's vacuum seal is gone.  
14 Failure to test and validate (or falsify) a theory is the very type of unscientific work that is barred  
15 under *Daubert* and Rule 702.  
16

17  
18 Realizing his original opinions were lacking, Kasbekar also submitted an untimely  
19 "rebuttal" Finite Element Analysis ("FEA") in an attempt to support (albeit after-the-fact) his  
20 theory that repeated stress on the fill tube weld caused it to crack. But, again, because he lacks  
21 cryogenic engineering experience and training, Kasbekar's FEA used incorrect inputs that failed  
22 to account for the cryogenic effects on the material at issue.<sup>5</sup> At bottom, both Kasbekar's causation  
23 opinion and his flawed and untimely FEA should be barred.  
24

---

25  
26 <sup>5</sup> Indeed, Dr. Miller reviewed Kasbekar's work and testified that Kasbekar would have failed the  
27 Heat Transfer class for junior level undergraduates at Wisconsin where Dr. Miller teaches the very  
28 elements of Kasbekar's calculation. *See* Dr. Miller's 12/14/20 Deposition at 54:13-25, attached to  
the Ringel Declaration as Exhibit J.

Second, Plaintiffs erred in attempting to support their interpretation of the California consumer expectation test with the disclosure of Dr. Wininger's opinions. Dr. Wininger cannot offer qualified and reliable testimony of the expectations of an ordinary user of Tank 4. He has never used a computer controlled cryogenic freezer, let alone an MVE 808, in his 25 plus years as a lab director. Indeed, he failed to offer any opinion at all on how PFC actually used Tank 4. Because Wininger does not offer an admissible opinion on these issues, he too should be barred.

**II. THE CHART MVE 808 CRYOPRESERVATION FREEZER AND ITS USE BY PFC DURING THE PERTINENT TIME PERIOD**

Chart's cryogenic engineering expert, Dr. Franklin Miller's report explains the operation and function of the Chart MVE 808 tank at issue:

The MVE 808AF-GB is a cryopreservation freezer cooler by liquid nitrogen (LN2). The freezer is essentially a vacuum insulated tank (dewar) with space to immerse biological material in liquid nitrogen. The LN2 boils away as heat leaks into the cold space through the insulation system and through the top when the lid is opened to add or remove material from the tank. As the LN2 boils away, it is replenished by a control system that automatically opens a valve allowing LN2 to flow into the freezer from a LN2 supply dewar connected to the freezer by a piping system. A control system automatically maintains the LN2 level between low and high fill levels that the end user programs. The control system also has a low-level alarm that sounds when the LN2 level drops below a value set by the end user. Additionally, the control system calculates the rate of LN2 use, in units of inches per day, to allow the end user to monitor the performance of the freezer insulation system.

(See Dr. Miller's Rule 26(a)(2)(B) report at p. 2, § A, attached to the Ringel Declaration as Exhibit H.)

Dr. Miller's report also identifies PFC's misuse of Tank 4 between February 15, 2018 and the events of March 3 and March 4, 2018. (Ringel Decl., Ex. H at pp. 3-6). In short, PFC unplugged the controller on February 15, 2018, which "disabled three key components of [Tank 4's] fail-safe design: filling, monitoring, and alarming. Pacific Fertility laboratory personnel



1 admitted that, by unplugging the freezer, [PFC] transferred responsibility for filling and  
 2 monitoring to human beings (specifically, the lab personnel), not the MVE 808AF-GB.” (*Id.* at p.  
 3 3, § D).

4 Chart has filed a motion for summary judgment contemporaneous with this *Daubert*  
 5 motion. In accordance with Fed. R. Civ. Pro. 10(c), Chart incorporates herein by reference its  
 6 statement of facts of the events of February 15, 2018 through March 4, 2018 at PFC’s lab from the  
 7 memorandum filed in support of that motion.  
 8

### 9 **III. THE LEGAL STANDARD FOR ADMISSIBILITY OF EXPERT TESTIMONY**

10 As the proponents of Kasbekar’s and Wininger’s opinions, Plaintiffs bear “the burden of  
 11 proving admissibility.” *Lust By & Through Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598  
 12 (9th Cir. 1996) (affirming summary judgment for the defendant and the district court’s exclusion  
 13 of the plaintiff’s expert’s causation opinion under *Daubert*); *Daubert*, 509 U.S. at 592 n. 10.  
 14 Expert opinion testimony is admissible only if it meets the standards set forth in Rule 702—“A  
 15 witness who is qualified as an expert by knowledge, skill, experience, training, or education” can  
 16 provide opinion testimony if:  
 17  
 18

- 19 a) the expert's scientific, technical, or other specialized knowledge will  
 20 help the trier of fact to understand the evidence or to determine a fact in  
 21 issue;
- 22 b) the testimony is based on sufficient facts or data;
- 23 c) the testimony is the product of reliable principles and methods; and
- 24 d) the expert has reliably applied the principles and methods to the facts of  
 25 the case.

26 Fed. R. Evid. 702.

27 In addition to ensuring an expert is qualified, the trial court’s “gatekeeper” function  
 28 requires screening the proffered opinions for reliability and relevance. *Daubert*, 509 U.S. at 589.  
 The Ninth Circuit has articulated the two-prong analysis as follows: First, the reliability inquiry

1 focuses on the expert's methodology, the demonstration of scientific knowledge and findings  
 2 derived by the scientific method, *i.e.*, work product that amounts to "good science." *Daubert v.*  
 3 *Merrell Dow Pharm.*, 43 F.3d 1311, 1315 (9th Cir. 1995) ("*Daubert II*") (citation and quotations  
 4 omitted). Second, the relevancy inquiry means the testimony must "fit" the facts of the case, *i.e.*,  
 5 "it logically advances a material aspect of the proposing party's case." *Id.*

#### 6 **IV. ARGUMENT**

##### 7 **A. Kasbekar's causation opinions and untimely FEA should be excluded.**

8 Turning to Kasbekar first, he is not a cryogenic engineer and lacks the necessary education,  
 9 training and experience in the design, manufacture and use of cryogenic storage devices required  
 10 to offer qualified opinions in this case. Given his lack of qualifications in this highly specialized  
 11 area of engineering, it is no surprise that Kasbekar did not test to either validate or falsify the crux  
 12 of his causation opinion: That Tank 4 experienced a rapid loss of liquid nitrogen (LN2) from a  
 13 complete vacuum seal loss between the afternoon of Saturday, March 3, 2018 and shortly after  
 14 noon on Sunday, March 4. That untested assumption, however, is the foundation of his theory  
 15 that an allegedly defective weld on Tank 4's fill line port resulted in a complete vacuum seal loss.  
 16 In his rebuttal report of December 4, 2020, Kasbekar attempted to bolster his weld-defect opinion  
 17 with an untimely FEA. That analysis, however, only served to underscore his lack of qualifications  
 18 to opine on these issues because he failed to properly calculate the cryogenic effects on the fill line  
 19 tube material at issue. Kasbekar's causation opinion amounts to junk science and, under *Daubert*  
 20 and its progeny, should be excluded from this case.

##### 21 **1. Kasbekar is not qualified to render opinions in cryogenic engineering** 22 **– the heart of the discipline at issue in this case.**

23 Kasbekar is not a cryogenic engineer. (Ringel Decl., Ex. C at 19:11-12). He does not  
 24

1 have an education in cryogenic engineering. (*Id.* at 7:18-20). He has never published any papers  
2 on cryogenic engineering or cryogenic storage tanks. (*Id.* at 27:18-20). He has never designed or  
3 developed a cryogenic freezer. (*Id.* at 19:13-20; 20:3-6). Nor does he hold himself out as an expert  
4 in the design of cryogenic tanks. (*Id.* at 25:24-26-7). Indeed, he has never before conducted a  
5 failure analysis of a cryogenic tank. (*Id.* at 11:20-21).

7       Rather, Kasbekar is a jack-of-all-trades mechanical engineer unqualified to opine on  
8 cryogenic matters. He simply does not have “expertise in the matters on which he will opine in  
9 this case.” *Wolf v. Hewlett Packard Co.*, No. 15-cv-01221, 2016 WL 7743692, at \*6 (C.D. Cal.  
10 Sept. 1, 2016) (finding an expert lacked sufficient statistical qualifications despite having a fairly  
11 strong statistical background); *see also Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 24 (D.  
12 Mass. 1995) (“Just as a lawyer is not by general education and experience qualified to give an  
13 expert opinion on every subject of the law, so too a scientist or medical doctor is not presumed to  
14 have expert knowledge about every conceivable scientific principle or disease.”); *Wilson v. Woods*,  
15 163 F.3d 935, 938 (5th Cir. 1999) (affirming the district court’s refusal to qualify a witness as an  
16 expert where the witness’s expertise “was no greater than that of any other individual with a  
17 general scientific background”).

20       Even though an expert, like Kasbekar, may be qualified in one area of expertise, he still  
21 may be precluded from offering opinions beyond that area of expertise, or that are not founded on  
22 a reliable methodology. *Kumho Tire v. Carmichael*, 526 U.S. 137, 154-55 (1999). Because  
23 Kasbekar’s opinions rest on insufficient qualifications about cryogenics, he should be excluded  
24 from testifying on this basis alone.

2. **Kasbekar's flawed methodology – untested and unreliable hypotheses.**

Kasbekar's inadequate cryogenic qualifications exacerbated his misunderstandings and the flawed methodologies he employed to reach his conclusion that an alleged defect in Tank 4 caused Plaintiffs' damages. Reliable and admissible expert opinions should be based on testing that validates or falsifies the proffered opinion: "Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry." *Daubert*, 509 U.S. at 593; *Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1422-1423 (9th Cir. 1998) (courts must focus on the soundness of the expert's methodology). The absence of reliable testing to support a hypothesis is a prime reason to exclude expert opinion testimony. *See Cabrera*, 134 F.3d at 1422-1423 (upholding rejection of expert testimony for lack of valid testing to support expert's opinion); *see also Lust*, 89 F.3d at 598.

Kasbekar's opinion that a total vacuum seal loss existed and caused the Plaintiffs' tissue loss is premised on two assumptions. First, that Tank 4 actually contained approximately 14 inches of LN2 on the afternoon of March 3, 2018. Second, that such a sufficient amount of LN2 evaporated by noon the following day of March 4:

The subject tank was reportedly filled on Saturday, March 3, 2018 at the end of the day, which was typically 2:00 p.m. on weekends.[] The tank failure was discovered at 12:20 p.m. on Sunday, March 4, 2018, less than 24 hours after the last fill. Based on the MVE 808 specifications and the testing performed by Chart, less than about 8 liters of LN2 should have evaporated during this time period. Given a fill level of 14 inches as documented and a height to volume relationship of 10.3 inches of LN2 per inch of fill height, the level should have decreased by less than 1 inch between the Saturday afternoon fill and the discovery of the failed tank on Sunday at 12:30 p.m.[] This analysis also assumes that the 14-inch fill covers the tank contents by at least 1 inch.[] If the tank vacuum jacket remained intact, then the LN2 evaporation should have been immaterial. However, if a vacuum jacket breach occurred resulting in the loss of

1 insulating ability and allowing LN2 to enter the vacuum space, then a  
2 significant decrease in the LN2 level would occur more rapidly than from  
normal evaporation.

3 (Ringel Decl., Ex. A at pp. 37-38). But Kasbekar should have tested to either falsify or validate  
4 whether approximately 14 inches of LN2 evaporates in a MVE 808 tank in less than 24 hours when  
5 a full vacuum seal loss exists.

6  
7 At deposition, Kasbekar conceded he did not conduct such testing:

8 Q. Could you have tested your theory that the liquid nitrogen evaporated  
between 2:30 on March 3rd and 12:30 on March 4?

9 A. Number one, I have no reason to do that and no real need to do that. And  
10 it's based upon assumptions of measurements taken by two people. That  
11 would be the error in any testing that was done. But the assumption I relied  
12 upon is that there was a reasonable supply of nitrogen in the tank the day  
before.

13 (Ringel Decl., Ex. D at 49:10-19). Kasbekar's "assumption" that "a reasonable supply" of LN2  
14 existed in Tank 4 as of March 3 is the starting point for his theory that a crack in a weld caused a  
15 rapid loss of LN2 between March 3 and March 4. If, however, there was not a reasonable supply  
16 of LN2 in Tank 4 as of March 3, then Kasbekar's hypothesized weld-crack-defect is irrelevant to  
17 the cause of the insufficient LN2 supply left in Tank 4 when PFC opened the Tank on March 4.  
18 Kasbekar acknowledged as much in his report: "If the tank vacuum jacket remained intact, then  
19 the LN2 evaporation should have been immaterial." (Ringel Decl., Ex. A at p. 38).

20  
21 In contrast to Kasbekar, Chart's cryogenic engineering expert, Dr. Miller, completed the  
22 necessary testing of Kasbekar's own hypothesis. Utilizing the scientific method, Miller's testing  
23 falsified the hypothesis that approximately 14 inches of LN2 evaporated from Tank 4 in less than  
24 24 hours even with a complete vacuum failure present. (Ringel Decl., Ex. H at pp. 13-22). The  
25 testing results also established that PFC personnel's purported 14-inch measurement of LN2 on  
26 the afternoon of March 3 is inaccurate. Thus, Kasbekar's starting "assumption" that Tank 4 started  
27  
28

1 the time period between March 3 and March with a “reasonable supply” of LN2 was also false.  
 2 Instead, Dr. Miller’s testing establishes that Tank 4 had run out of LN2 supply before March 4,  
 3 which, in Kasbekar’s words, renders his hypothesized weld-crack cause of a complete vacuum  
 4 failure “immaterial.”

5 Kasbekar’s starting “assumption” that a “reasonable supply” of LN2 existed in Tank 4 as  
 6 of March 3 is problematic for another reason. He failed to account for the obvious and alternative,  
 7 non-product defect cause of insufficient LN2 supply left in Tank 4: that PFC, after unplugging  
 8 the controller on February 15, 2018, failed to manually supply enough LN2 to Tank 4 to make up  
 9 for the natural evaporation of LN2 and maintain cryogenic storage of Tank 4’s contents. Ninth  
 10 Circuit law on this issue is well established: An expert proffering a causation opinion must  
 11 consider and rule out other possible causes for the occurrence. *Claar v. Burlington Northern R.*  
 12 *Co.*, 29 F.3d 499, 502 (9th Cir. 1994).<sup>6</sup>

13 The Supreme Court decision in *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999),  
 14 further underscores this additional ground for exclusion of Kasbekar’s opinion. In *Kumho*, the  
 15 Supreme Court held that the trial court did not abuse its discretion in excluding the  
 16 technical/engineering testimony of the plaintiff’s tire-failure analyst. *See id.* at 158. The plaintiff’s  
 17 expert also acknowledged there were plausible, non-defect related reasons for a tire to experience  
 18 a blowout. *Id.* at 154-155. In upholding the trial court’s exclusion of the expert opinion that a  
 19

20  
 21  
 22  
 23 <sup>6</sup> Kasbekar’s causation opinion falls short of satisfying other *Daubert* factors for reliability. *See*  
 24 *Daubert*, 509 U.S. at 594. For example, he concedes there is no known or potential rate of error  
 25 for his conclusion based on the methods he employed. (Ringel Decl., Ex. D at 38:17-20). In key  
 26 respects, Kasbekar’s defective-weld causation opinion is a classic example of an expert starting  
 27 with the end-result in mind instead of applying the scientific method to the facts to determine the  
 28 outcome. *See Mitchell v. Gencorp, Inc.*, 165 F.3d 778, 785 (10th Cir. 1999) (“Instead of reasoning  
 known facts to reach a conclusion, the experts ... reasoned from an end result in order to  
 hypothesize what needed to be known but what was not”).

defect caused the blowout, the Supreme Court held that “[t]he relevant issue was whether the expert could reliably determine the cause of *this* tire’s separation.” *Id.* at 154. Like Kasbekar’s opinion testimony here, the plaintiff’s expert’s causation opinion in *Kumho* rested on a series of subjective and untested assumptions. *See id.* at 143-144. With that unreliable causation opinion excluded, the trial court properly granted summary judgment for the tire manufacturer. *Id.* at 158. The result here should be no different—Kasbekar’s opinion that any alleged defect in Tank 4 caused a complete vacuum seal failure and rapid loss of LN2 should be excluded.

Indeed, excluding Kasbekar’s causation opinion here for lack of reliability would be on all fours with the results of two other recent product liability cases where he was barred from offering expert opinions. *See Hickerson v. Yamaha Motor Corp.*, 882 F.3d 476, 482 (4th Cir. 2018) (affirming district court’s exclusion of Kasbekar’s warning defect opinion as unreliable under *Daubert*), cert. denied sub nom. *Hickerson v. Yamaha Motor Corp., U.S.A.*, 139 S. Ct. 105 (2018); *Wells v. Kawasaki Motors Corp., U.S.A.*, No. 2:16-CV-01086-DN, 2019 WL 5842921, \*4 (D. Utah Nov. 7, 2019) (excluding Kasbekar’s defect opinion as unreliable under *Daubert*).

### **3. Kasbekar’s flawed and untimely FEA**

In his rebuttal report of December 4, 2020, Kasbekar supplies the results of his FEA to illustrate thermally induced cyclic stress based on thermal contraction of the fill line tube connected to the weld claimed to be insufficiently robust and, therefore, defective. (Ringel Decl., Ex. B at pp. 7-13). But the inputs he used for the FEA failed to accurately account for the cryogenic effects of LN2 on the fill line tube material at issue. Kasbekar used incorrect thermal boundary conditions by assuming the temperature of the entire 26 inch tube changes from room temperature to cryogenic LN2 temperature with each fill cycle. This is a common mistake made by engineers lacking cryogenic experience and training. *See* Dr. Miller’s 12/11/20 Rebuttal Report



at p. 2, attached to Ringel Declaration as Exhibit I.

Contrary to Kasbekar's assumption, approximately 10 inches of the fill line tube remains filled with LN2 throughout each fill cycle and, therefore, only approximately 16 inches of the 26 inch tube experience temperature fluctuation. (*Id.* at p. 2).<sup>7</sup> During a fill cycle, all 26 inches of the tube are filled with LN2. In other words, 10 inches of the 304 stainless steel fill tube remains at a constant approximately -196 degrees Celsius (cryogenic temperatures). Dr. Kasbekar, however, inputted a room temperature for all 26 inches of this part and then cooled it to LN2 temperatures, *see* (Ringel Decl., Ex. E at 11:18-14:1, 15:9-14), rendering his FEA simply wrong and irrelevant. (Ringel Decl., Ex. I at pp. 2-4). He also failed, among other things, to take into account that the material at issue, 304 stainless steel, has stress properties that improve at cryogenic temperatures. (Ringel Decl., Ex. I at pp. 3-4). Contrary to Kasbekar's inadmissible say-so, these facts significantly impact the inputs for a reliable FEA on the forces loaded on the fill line tube weld at issue. The results of a proper FEA demonstrate load forces reduced by a factor of five, which are not capable of producing the type of cyclic-induced weld fracture Kasbekar hypothesized occurred here. (Ringel Decl., Ex. I at p. 3)(*see also* Ringel Decl., Ex. K at pp. 4-7).

In addition to the obvious conundrum Kasbekar caused by starting with the wrong inputs, his FEA output runs into the "fit" roadblock to admissibility. *Daubert*, 509 U.S. at 591. This is the very type of misleading "science" that court's exclude. "Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in

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<sup>7</sup> Because the tube's fill port is approximately 1 inch above the false bottom of the tank, 16 inches is the actual length of the tube not filled with LN2 when the tank is filled with 11 inches of LN2. Thus, when the tank has 11 inches of LN2 inside, 10 inches of the 26 inch fill tube is filled with LN2. In other words, Miller's use of 16 inches is based on the fact that the tank fill level is measured from the false bottom which is 1 inch below the fill tube's port.



1 weighing possible prejudice against probative force under Rule 403 of the present rules exercises  
 2 more control over experts than over lay witnesses.” *Id.* at 595 (citation and quotation signals  
 3 omitted). “Federal judges must therefore exclude proffered scientific evidence under Rules 702  
 4 and 403 unless they are convinced that [the evidence] speak clearly and directed to an issue in  
 5 dispute in the case, and that it will not mislead the jury.” *Daubert II*, 43 F.3d at 1321 n.17. An  
 6 FEA based on incorrect data simply does not “fit” the facts of the case and is therefore  
 7 inadmissible.  
 8

9 As instructed in *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), nothing in either  
 10 *Daubert* or Rule 702 “requires a district court to admit opinion evidence that is connected to  
 11 existing data only by the *ipse dixit* of the expert.” *Id.* at 146. Because Kasbekar offers nothing but  
 12 his own flawed say-so that the fill line tube data he used is proper, his FEA outputs are not  
 13 admissible.  
 14

15 Procedural grounds also exist to exclude Kasbekar’s FEA. The FEA was disclosed as a  
 16 rebuttal opinion on December 4, 2020. But the FEA is not “solely” to rebut opinions offered by  
 17 Chart’s experts. *See* Fed. R. Civ. P. 26(a)(2)(D)(ii). Rather, the FEA attempts to bolster  
 18 Kasbekar’s original weld-defect opinion. As such, the FEA should have been completed and  
 19 disclosed in accordance with Rule 26(a)(2)(B) by November 6, 2020, the deadline for Plaintiffs’  
 20 disclosure of expert reports. Under Rule 37(c)(1),  
 21

22 [i]f a party fails to provide information ... as required by Rule 26(a) or (e),  
 23 the party is not allowed to use that information ... to supply evidence on a  
 24 motion, at a hearing, or at a trial, unless the failure was substantially  
 25 justified or is harmless.

26 Rule 37(c)(1)’s exclusionary sanction is “self-executing” and “automatic” and is “designed to  
 27 provide a strong inducement for disclosure” and does not require a finding of willfulness or bad  
 28

1 faith. *Yeti by Molly Ltd.*, 259 F.3d 1101, 1106 (9th Cir. 2001) (citing the Advisory Committee  
2 Notes for Rule 37(c)(1)); *see also Goodman v. Staples The Office Superstore, LLC*, 644 F.3d 817,  
3 827 (9th Cir. 2011).

4 Here, Plaintiffs' late disclosure of Kasbekar's FEA is not substantially justified or harmless  
5 and it is unfairly prejudicial to Chart. Rule 26(a)(2)(B)(i) requires that an expert's opening report  
6 contain a "complete statement of all opinions to be expressed and the basis and reasons for them."  
7 *See also Walter Int'l Prods., Inc. v. Salinas*, 650 F.3d 1402, 1410 (11th Cir. 2011); *Sierra Club v.*  
8 *Cedar Point Oil Co.*, 73 F.3d 546, 571 (5th Cir. 1996). The late disclosure of Kasbekar's FEA  
9 prevented Chart from inquiring about it at his November 25, 2020 deposition. The cascade of  
10 events and prejudice that follows when a plaintiff's liability expert does not comply with the rules  
11 for timely disclosing all of the support for opinions cannot be understated, especially in a product  
12 liability case where the plaintiff bears the burden of proof and yet simultaneous expert disclosures  
13 are in place. Chart's experts were prevented from rebutting the FEA by December 4, 2020, the  
14 original rebuttal report deadline. Under the circumstances, Chart's experts had no choice but to  
15 complete rebuttals of the faulty FEA and submit additional rebuttal reports disclosed on December  
16 8 and 11, respectively.

17 At bottom, Kasbekar's untimely FEA fundamentally contradicts Rule 26, which contains  
18 no loophole through which a party who submits partial expert opinions, "or who wishes to revise  
19 her expert's opinions in light of her opponent's challenges to the analysis and conclusions therein,  
20 can add to them to her advantage after the court's deadline for doing so has passed." *See Luke v.*  
21 *Family Care and Urgent Medicine Clinics*, 323 Fed. Appx. 496, 500 (9th Cir. 2009).

**B. Wininger’s opinions on causation and the safety expectations of PFC should be excluded.**

Wininger concludes that there was (a) a sudden vacuum loss that occurred overnight between March 3 and March 4, 2018, (b) Tank 4 failed to perform as safely as an ordinary user expects and (c) the incident damaged Plaintiffs’ tissue in Tank 4. (Ringel Decl., Ex. G at 37:3-4, 22-24, 68:2-5); (Ringel Decl., Ex. F at pp. 14-16, ¶¶ 37-42). Ostensibly, Wininger’s opinions are to support an alternative theory of design defect under California products liability law—the consumer expectation test. But Wininger is not qualified to render product defect and causation opinions and his end-user-safety-expectation opinion lacks a reliable foundation. Nor does Wininger account for the end-user PFC’s actual use (or misuse) of Tank 4 leading up to March 4, 2020. Much like Kasbekar, Wininger’s opinions are riddled with admissibility problems and should be excluded.

**1. Wininger is not qualified to offer opinions on either causation or the safety expectations of a user of an MVE 808 tank.**

As Plaintiffs’ own counsel rightly acknowledged during his deposition, Wininger “is an embryologist,” “not an engineer put forth to opine on the mechanical failure of the tank.” (Ringel Decl., Ex. G at 37:11-13). Wininger admits he has no experience with vacuum failure at his laboratories and, despite concluding that rapid vacuum loss occurred here, “does not really know how fast [rapid vacuum failure] can occur.” (Ringel Decl., Ex. G at 64:5-9; 69:9-11). He has no personal experience with an MVE 808 or a computer controlled cryogenic tank, such as Tank 4. (*Id.* at 42:21-25, 43:3-4). He does not know how long it takes to fill an MVE 808 using a TEC 3000 controller or what an embryologist considers an “excessively long fill time.” (*Id.* at 56:9-14).

Wininger is also not qualified to opine that Tank 4 failed to perform as safely as an ordinary user would expect. He has no personal experience with an MVE 808 and has never used a

1 controller on a large dewar, such as the MVE 808. (Ringel Decl., Ex. G at 42:21-25, 43:3-4). He  
 2 has never even worked in a lab with a computer-controlled cryogenic storage tank. (*Id.* at 43:10).  
 3 He does not have any personal knowledge of how long it takes to fill an MVE 808 using a TEC  
 4 3000 controller. (*Id.* at 56:9). He does not personally know what is considered an excessively long  
 5 fill time for an MVE 808 using a TEC 3000 controller. (*Id.* at 56:14). Wininger does not have  
 6 experience with LN2 plumbing supply systems like the system in use at PFC. (*Id.* at 57:13-21). He  
 7 does not know the configuration of the pipes connecting Tank 4 and the LN2 supply. (*Id.* at 57:13-  
 8 21). He has never seen a LN2 supply cylinder lose pressure. (*Id.* at 70:8-9). His laboratories  
 9 manually re-fill the LN2 tanks. (*Id.* at 57:25). Moreover, his laboratories do not maintain “long-  
 10 term” storage of eggs and embryos. (*Id.* at 57:25). Instead, his laboratories send the tissue off-site  
 11 to third party storage facilities. (*Id.* at 14:1-20).

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 14 Based on lack of qualifications alone, Wininger’s opinions should be excluded.

15 **2. Wininger’s opinions are conclusory and predicated on unverified**  
 16 **assumptions and are therefore unreliable and irrelevant.**

17 While experts can provide opinions on the expectations of an end user of a product in  
 18 certain limited contexts under California products liability law, Chart maintains the consumer  
 19 expectation test is wholly inappropriate for the circumstances of this case involving the use of a  
 20 computer controlled MVE 808 cryopreservation freezer cooled by LN2 to store biological tissue.  
 21 The consumer expectations test is reserved for cases in which “the everyday experience of the  
 22 product’s user permits a conclusion that the product’s design violated minimum safety  
 23 assumptions,” regardless of the merits of the design. *Soule v. General Motors Corp.*, 8 Cal. 4th  
 24 548, 567 (1994). A complex product can “cause injury in a way that does not engage its ordinary  
 25 consumers’ reasonable minimum assumptions about safe performance.” *Id.* at 566-567. In such  
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 27  
 28

1 cases, the consumer expectations test does not apply. *Id.* at 568; *see also Morson v. Superior Court*,  
 2 90 Cal. App. 4th 775, 793-795 (2001).

3 Assuming, for argument's sake, that the consumer expectation applies here and that PFC's  
 4 use of Tank 4 warrants an expert's opinion on the safety expectations of PFC, Wininger has failed  
 5 to supply an admissible opinion. Wininger offers the following conclusions couched as an  
 6 "opinion":  
 7

8 Users of cryogenic tanks, like myself, also do not expect them to suffer a  
 9 sudden and total loss of vacuum insulation (as opposed to a gradual  
 10 degradation of the vacuum layer). Nor do they expect that the tank could  
 11 consume more than 14 inches of liquid nitrogen in less than 24 hours—  
 12 which is what happened to Tank 4.

13 (Ringel Decl., Ex. F at p. 14, ¶ 37). This "opinion" assumes its foundation "is what happened":  
 14 that a total vacuum loss occurred resulting in the consumption of 14 inches of LN2 in less than 24  
 15 hours. Wininger has simply parroted the untested causation hypothesis offered by Kasbekar. In  
 16 reality, Wininger stops short of offering support for his conclusion that the safety expectations of  
 17 PFC were not met. Indeed, he discloses no opinion at all on whether PFC personnel complied with  
 18 the standard of care in their use of Tank 4. (Ringel Decl., Ex. G at 27:8-11).

19 Wininger's decision to ignore key data and alternative explanations for what happened with  
 20 Tank 4 renders the reliability of his "testimony's factual basis" unsound. *See Kumho Tire Co.*, 526  
 21 U.S. at 149. For example, Wininger's report and deposition testimony are silent on PFC's decision  
 22 to unplug Tank 4's controller and alarm system on February 15, 2018, not seek an immediate  
 23 diagnostic evaluation, and, instead, initiate manual LN2 fill cycles. Nor does Wininger comment  
 24 on PFC's egregious decision to backdate data recordings of LN2 level measurements during the  
 25 pertinent time period. Wininger even concedes he is unaware of any testing of the evaporation  
 26 rate of LN2 in an MVE 808 tank with a compromised vacuum seal. (Ringel Decl., Ex. G at 39:20).  
 27  
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1 Instead, Wininger simply reached this conclusion by accepting as true a PFC employee’s testimony  
2 that a fill cycle was initiated and a measurement of 14 inches of LN2 in Tank 4 was taken on  
3 March 3. (Ringel Decl., Ex. G at 41:16). Wininger cannot have it both ways – on one hand, he  
4 offers the opinion that the safety expectations of the user of Tank 4 were not met, but, on the other  
5 hand, he refuses to comment on how PFC actually used the tank in the first place.  
6

7 In sum, Wininger’s decision to ignore unfavorable facts creates an unacceptable “analytical  
8 gap,” which is a red flag indicator of an unscientific, inadmissible opinion contrived for litigation  
9 purposes. *Joiner*, 522 U.S. at 146; *Claar*, 29 F.3d at 502-03; *Barber v. United Airlines, Inc.*, 17 F.  
10 App’x 433, 437 (7th Cir. 2001) (affirming exclusion of an aviation expert who “cherry-picked the  
11 facts he considered to render an expert opinion” without “explain[ing] why he ignored certain facts  
12 and data, while accepting others.” As the court explained, “such a selective use of facts fails to  
13 satisfy the scientific method and *Daubert*.”). Wininger’s safety expectations opinion should be  
14 excluded.  
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V. **CONCLUSION**

For all of the foregoing reasons, Chart requests that the Court grant its *Daubert* motion to exclude the opinion testimony of Plaintiffs' experts, Dr. Anand Kasbekar and Dr. David Wininger.

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Respectfully submitted,

By: /s/ Kevin Ringel

John J. Duffy (SB No. 6224834)  
Kevin M. Ringel (SB No. 6308106)  
Margaret C. Redshaw (SB No. 6327480)  
**SWANSON, MARTIN & BELL, LLP**  
330 N Wabash, Suite 3300  
Chicago, Illinois 60611  
Tel: (312) 321-9100; Fax: (312) 321-0990  
jduffy@smbtrials.com  
kringel@smbtrials.com  
mredshaw@smbtrials.com

Marc G. Cowden (SB No. 169391)  
Adam Stoddard (SB No. 272691)  
**SHEUERMAN, MARTINI, TABARI, ZENERE  
& GARVIN**  
1033 Willow Street  
San Jose, California 95125  
Tel: (408) 288-9700; Fax: (408) 295-9900  
mcowden@smtlaw.com  
astoddard@smtlaw.com

*Counsel for Defendant Chart, Inc.*